IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

AIDA CARLO, on behalf of herself and all others similarly situated, Plaintiff, v. STRIDES PHARMA, INC., Defendant.	Civil Action No. **CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff Aida Carlo ("Plaintiff") brings this action on behalf of herself and all others similarly situated against Strides Pharma, Inc. ("Strides" or "Defendant"). Plaintiff makes the following allegations pursuant to the investigation of her counsel and based upon information and belief, except as to the allegations specifically pertaining to herself, which are based on personal knowledge.

NATURE OF THE ACTION AND FACTS COMMON TO ALL CLAIMS

1. This is a class action lawsuit regarding Strides's manufacturing of ranitidine-based prescription medications that contain dangerously high levels of N-nitrosodimethylamine ("NDMA"), a carcinogenic and liver-damaging impurity.

2. Ranitidine is an over-the-counter and prescription medication that is designed to decrease the amount of acid created by the stomach. Ranitidine is intended to be used for the treatment of heartburn associated with indigestion and sour stomach. However, Strides's manufacturing process has caused its ranitidine medications to contain dangerously high levels of NDMA.

3. NDMA is a semivolatile organic chemical. According to the U.S. Environmental Protection Agency, NDMA "is a member of N-ni-trosamines, a family of potent carcinogens."

While NDMA is not currently produced in the United States other than for research purposes, it was formerly used "in production of liquid rocket fuel," among other uses. NDMA is listed as a "priority toxic pollutant" in federal regulations. *See* 40 CFR § 131.36. Exposure to NDMA can cause liver damage and cancer in humans. NDMA is classified as a probable human carcinogen, and animal studies have shown that "exposure to NDMA has caused tumors primarily of the liver, respiratory tract, kidney and blood vessels."

4. On September 13, 2019, the FDA issued a statement announcing the presence of NDMA in ranitidine-containing medications.[1] The FDA's notice states that "NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests." Since then, the FDA's own testing "has found unacceptable levels of NDMA in samples of ranitidine."[2]

5. Further, on April 1, 2020, the FDA requested that all ranitidine "manufacturers to withdraw all prescription and over-the-counter (OTC) ranitidine drugs from the market immediately."[3] This decision was made because FDA "determined that the impurity in some ranitidine products increases over time and when stored at higher than room temperatures may

[1] Food & Drug Admin., Statement Alerting Patients and Health Care Professionals of NDMA Found in Samples of Ranitidine (Sept. 13, 2019), https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine.

[2] Food & Drug Admin., 10/2/19: UPDATE – FDA Provides Update on Testing of Ranitidine for NDMA Impurities (Oct. 2, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[3] Food & Drug Admin., All Ranitidine Products (Zantac): Press Release – FDA Requests Removal (Apr. 1, 2020), https://www.fda.gov/safety/medical-product-safety-information/all-ranitidine-products-zantac-press-release-fda-requests-removal?utm_campaign=FDA%20MedWatch%20-%20All%20Ranitidine%20Products%20%28Zantac%29&utm_medium=email&utm_source=Eloqua (last accessed Apr. 21, 2020).

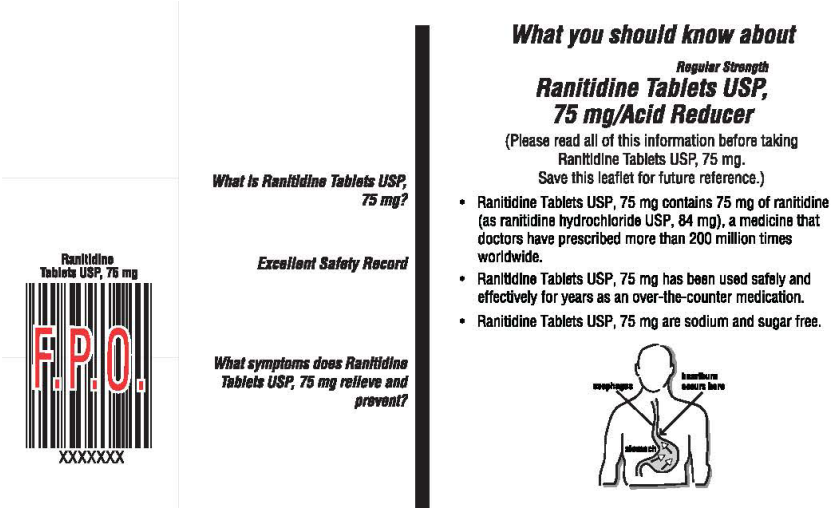
result in consumer exposure to unacceptable levels of this impurity."[4]

6. On September 27, 2019, Strides halted sales of its ranitidine medications after the FDA asked Strides to test the drug for NDMA.[5] Strides never issued a formal recall prior to the FDA's mandate.

A. Strides Markets Its Ranitidine Medications As Safe

7. Strides marketed its ranitidine medications as safe and effective products.

8. On the insert for Strides's 75 mg Ranitidine Tablet, Strides touts that "Ranitidine Tablets…ha[ve] been used safely and effectively for years as an over-the-counter medication."



9. The insert also notes that ranitidine has been "prescribed more than 200 million times worldwide" and is next to the heading, "Excellent Safety Record."

10. In short, when consumers purchase or are prescribed ranitidine medications manufactured by Strides, they expect that the medications will be safe and effective for the purpose for which it is purchased. They do not expect, and Defendant does not disclose, that the

[4] *Id*.

[5] Nallur Sethuraman, *India's Strides Pharma Halts U.S. Sales of Heartburn Drug*, REUTERS, Sept. 27, 2019, https://www.reuters.com/article/us-strides-pharma-ranitidine/indias-strides-pharma-halts-us-sales-of-heartburn-drug-idUSKBN1WC0PU (last visited Oct. 31, 2019).

medications contain the harmful impurity NDMA.

B. Strides's Ranitidine Medications Contain Dangerous Levels Of NDMA

11. Contrary to the above assertions, Strides's ranitidine medications contain dangerously high levels of NDMA that would not be present if the medications were properly synthesized. As noted in paragraph 4 and 5, *supra*, the FDA has found unacceptable levels of NDMA in samples of ranitidine.

12. Further, on April 1, 2020, the FDA requested that all ranitidine "manufacturers to withdraw all prescription and over-the-counter (OTC) ranitidine drugs from the market immediately."[6] This decision was made because the FDA "determined that the impurity in some ranitidine products increases over time and when stored at higher than room temperatures may result in consumer exposure to unacceptable levels of this impurity."[7]

13. The Medicines and Healthcare Products Regulatory Agency of the United Kingdom has issued an alert regarding ranitidine medications, noting recalls issued by companies are "a precautionary measure due to possible contamination of the active substance in Zantac, ranitidine, with an impurity called NDMA."[8] "The MHPRA has asked manufacturers to quarantine all ranitidine products which may contain the active pharmaceutical ingredient that is

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[6] Food & Drug Admin., All Ranitidine Products (Zantac): Press Release – FDA Requests Removal (Apr. 1, 2020), https://www.fda.gov/safety/medical-product-safety-information/all-ranitidine-products-zantac-press-release-fda-requests-removal?utm_campaign=FDA%20MedWatch%20-%20All%20Ranitidine%20Products%20%28Zantac%29&utm_medium=email&utm_source=Eloqua (last accessed Apr. 21, 2020).

[7] *Id*.

[8] Medicine and Healthcare Regulatory Agency, Zantac – MHRA Drug Alert Issued as GlaxoSmithKline Recalls all Unexpired Stock (Oct. 8, 2019), https://www.gov.uk/government/news/zantac-mhra-drug-alert-issued-as-glaxosmithkline-recalls-all-unexpired-stock (last accessed Apr. 21, 2020).

potentially affected by this issue."[9]

14. While the cause of the NDMA contamination in ranitidine medications is still being investigated by the FDA and other regulatory agencies. However, the Health Products Regulatory Authority of Ireland, in issuing a recall of ranitidine medications, has stated: "The reason for the recall is that a nitrosamine impurity has been identified in ranitidine active substance batches manufactured at a manufacturing site in India."[10]

15. The FDA has established a "permissible daily intake limit for…NDMA of 96 [nanograms]."[11] But Strides Ranitidine has an NDMA content of nearly 3 million nanograms *per tablet*, according to testing by Valisure, an FDA-registered online pharmacy.[12]

150 mg Tablets or equivalent	Lot #	NDMA per tablet (ng)
Ranitidine, Strides	77024060A	2,951,649

16. Further, on April 1, 2020, the FDA requested that all ranitidine "manufacturers to withdraw all prescription and over-the-counter (OTC) ranitidine drugs from the market immediately."[13] This decision was made because FDA "determined that the impurity in some

[9] *Id*.

[10] Health Products Regulatory Authority, Precautionary Pharmacy and Retail Level Recall of Several Batches of a Number of Ranitidine Medicines in Ireland (Sept. 23, 2019), https://www.hpra.ie/homepage/medicines/safety-notices/item?t=/precautionary-pharmacy-and-retail-level-recall-of-several-batches-of-a-number-of-ranitidine-medicines-in-ireland&id=d26b0c26-9782-6eee-9b55-ff00008c97d0 (last accessed Apr. 21, 2020).

[11] VALISURE, VALISURE CITIZEN PETITION ON RANITIDINE 1 (2019), https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf (last visited 10/14/19) (hereinafter "VALISURE PETITION").

[12] *Id*. at 6.

[13] Food & Drug Admin., All Ranitidine Products (Zantac): Press Release – FDA Requests Removal (Apr. 1, 2020), https://www.fda.gov/safety/medical-product-safety-information/all-ranitidine-products-zantac-press-release-fda-requests-removal?utm_campaign=FDA%20MedWatch%20-%20All%20Ranitidine%20Products%20%28Zantac%29&utm_medium=email&utm_source=Eloqua (last accessed Apr. 21, 2020).

ranitidine products increases over time and when stored at higher than room temperatures may result in consumer exposure to unacceptable levels of this impurity."[14]

C. Plaintiff Was Harmed By Purchasing Or Being Prescribed And Consuming Defective Ranitidine Medications Manufactured By Defendant

17. Plaintiff and the Class and Subclass were injured by the full purchase price of their Strides ranitidine medications. These medications are worthless, as they contain harmful levels of NDMA. This is underscored by Strides's voluntary recall of ranitidine medications "because of potential N-Nitrosodimethylamine (NDMA) amounts above levels established by the FDA," and its instruction to consumers to "stop using the product."[15] As the medications expose users to NDMA well above the legal limit, the medications are not fit for human consumption. Plaintiff is further entitled to statutory damages, damages for the injury sustained in consuming high levels of acutely-toxic NDMA, and for damages related to Defendant's conduct.

18. Plaintiff brings this action on behalf of herself and the Class and New York Subclass for equitable relief and to recover damages and restitution for: (i) breach of the implied warranty of merchantability, (ii) violation of New York General Business Law § 349, (iii) violation of New York General Business Law § 350, (iv) unjust enrichment, (v) fraudulent concealment, (vi) fraud, and (vii) conversion.

PARTIES

19. Plaintiff Aida Carlo is a citizen of New York who resides in Bronx, New York.

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[14] *Id*.

[15] Food & Drug Admin., Strides Pharmaceuticals, LLC. Issues Voluntary Nationwide Recall of Ranitidine Tablets, USP, 150mg and 300mg, and Ranitidine Syrup (Ranitidine Oral Solution, USP), 15 mg/mL, Due to Possible Presence of N-nitrosodimethylamine (NDMA) Impurity (Nov. 22, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/strides-pharmaceuticals-llc-issues-voluntary-nationwide-recall-ranitidine-tablets-usp-150mg-and-300mg (last accessed Apr. 21, 2020).

During all relevant time periods, Ms. Carlo was prescribed and consumed ranitidine medications manufactured by Strides. Ms. Carlo originally learned about the ranitidine defect through news sources reporting NDMA in ranitidine medications. When purchasing her ranitidine medications manufactured by Defendant, Ms. Carlo reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the ranitidine medication she consumed were properly manufactured and free from carcinogenic contaminants such as NDMA. Ms. Carlo relied on these representations and warranties in deciding to consume her ranitidine medication from Strides, and these representations and warranties were part of the basis of the bargain, in that she would not have purchased her ranitidine medication manufactured by Defendant at all, or would have only been willing to pay a substantially reduced price for her ranitidine medication, if she had known that it was not, in fact, properly manufactured, and contained the carcinogenic impurity NDMA. Ms. Carlo understood that each purchase involved a direct transaction between herself and Strides because her medication came with packaging and other materials prepared by Strides, including representations and warranties that her medication was properly manufactured, free from carcinogenic impurities such as NDMA, and safe for use.

20. Defendant Strides Pharma, Inc. is a New Jersey corporation with a principal place of business at 2 Tower Center Boulevard, Suite 1102, East Brunswick, New Jersey 08816. Strides Pharma, Inc. is a wholly owned subsidiary of Indian company Strides Pharma Science Limited, and is the front-end company for Strides's operations in the United States. Strides conducts substantial business in the United States, including in the State of New York. Strides has been engaged in the manufacturing of defective ranitidine throughout the United States, including in the State of New York.

JURISDICTION AND VENUE

21. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below, is a citizen of a different state than Defendant, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds $5,000,000 exclusive of interest and costs.

22. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because many of the acts and transactions giving rise to this action occurred in this District, and because Defendant (a) is authorized to conduct business in this District and has intentionally availed itself of the laws and markets within this District through the promotion, marketing, distribution, and sale of defective ranitidine in this District; (b) conducts substantial business in this District; and (c) is subject to personal jurisdiction in this District.

CLASS ALLEGATIONS

23. Plaintiff seeks to represent a class defined as all persons in the United States who purchased or were prescribed ranitidine-containing medications manufactured by Strides (the "Class"). Specifically excluded from the Class are persons who made such purchase for the purpose of resale, Defendant, Defendant's officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendant, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendant and/or Defendant's officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

24. Plaintiff also seeks to represent a subclass of all Class members who purchased in New York ranitidine-containing medications manufactured by Strides (the "New York

Subclass").

25. Subject to additional information obtained through further investigation and discovery, the foregoing definitions of the Class and New York Subclass may be expanded or narrowed by amendment or amended complaint.

26. **Numerosity.** The members of the Class and New York Subclass are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiff reasonably estimates that there are hundreds of thousands of members in the Class and tens of thousands of members in the New York Subclass. Although the precise number of members in the Class and New York Subclass is unknown to Plaintiff, the true number of members in the Class and New York Subclass is known by Defendant and may be determined through discovery. Members of the Class and New York Subclass may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendant and third-party retailers and vendors.

27. **Existence and predominance of common questions of law and fact.** Common questions of law and fact exist as to all members of the Class and New York Subclass and predominate over any questions affecting only individual members of the Class and New York Subclass. These common legal and factual questions include, but are not limited to, the following:

(a) whether the ranitidine medications manufactured by Defendant contain dangerously high levels of NDMA, thereby breaching the express and implied warranties made by Defendant and making the ranitidine-containing medications unfit for human consumption and therefore unfit for their intended purpose;

(b) whether Defendant knew or should have known that the ranitidine-containing medications contained elevated levels of NDMA prior to selling the medications, thereby constituting fraud and/or fraudulent concealment;

(c) whether Defendant has unlawfully converted money from Plaintiff and the Class and New York Subclass;

(d) whether Defendant is liable to Plaintiff and the Class and New York Subclass for unjust enrichment;

(e) whether Defendant is liable to Plaintiff and the Class and New York Subclass for fraudulent concealment;

(f) whether Defendant is liable to Plaintiff and the New York Subclass for violations of New York consumer-protection laws;

(h) whether Defendant is liable to Plaintiff and the Class and New York Subclass for breaches of express and implied warranties;

(i) whether Plaintiff and the Class and New York Subclass have sustained monetary loss and the proper measure of that loss;

(j) whether Plaintiff and the Class and New York Subclass are entitled to declaratory and injunctive relief;

(k) whether Plaintiff and the Class and New York Subclass are entitled to restitution and disgorgement from Defendant; and

(l) whether the marketing, advertising, packaging, labeling, and other promotional materials for the ranitidine-containing medications are deceptive.

28. **Typicality.** Plaintiff's claims are typical of the claims of the other members of the Class and New York Subclass in that Defendant mass marketed and sold defective ranitidine-

based medications to consumers throughout the United States. This defect was present in all of the ranitidine-containing medications manufactured, distributed, and sold by Defendant. Therefore, Defendant breached its express and implied warranties to Plaintiff and members of the Class and New York Subclass by manufacturing, distributing, and selling the defective ranitidine-containing medications. Plaintiff's claims are typical in that they and members of the Class and New York Subclass were uniformly harmed in purchasing and consuming the defective ranitidine-containing medications. Plaintiff's claims are further typical in that Defendant deceived Plaintiff in the very same manner as they deceived each member of the Class and New York Subclass. Further, there are no defenses available to Defendant that are unique to Plaintiff.

29. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the Class and New York Subclass. Plaintiff has retained counsel that is highly experienced in complex consumer class action litigation, and Plaintiff intends to vigorously prosecute this action on behalf of the Class and New York Subclass. Furthermore, Plaintiff has no interests that are antagonistic to those of the Class and New York Subclass.

30. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual members of the Class and New York Subclass are relatively small compared to the burden and expense of individual litigation of their claims against Defendant. It would, thus, be virtually impossible for the Class and New York Subclass, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if members of the Class and New York Subclass could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments

arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

31. In the alternative, the Class and New York Subclass may also be certified because:

(a) the prosecution of separate actions by individual members of the Class and New York Subclass would create a risk of inconsistent or varying adjudications with respect to individual members of the Class and New York Subclass that would establish incompatible standards of conduct for the Defendant;

(b) the prosecution of separate actions by individual members of the Class and New York Subclass would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other members of the Class and New York Subclass not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or

(c) Defendant has acted or refused to act on grounds generally applicable to members of the Class and New York Subclass as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class and New York Subclass as a whole.

COUNT I
Breach Of The Implied Warranty Of Merchantability
(On Behalf Of The Class And New York Subclass)

32. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

33. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and the New York Subclass against Defendant.

34. Defendant, as the designer, manufacturer, marketer, distributor, and/or seller, impliedly warranted that the ranitidine medications (i) would not contain elevated levels of NDMA and (ii) are generally recognized as safe for human consumption.

35. Defendant breached the warranty implied in the contract for the sale of the defective ranitidine medications because they could not pass without objection in the trade under the contract description, the ranitidine medications were not of fair or average quality within the description, and the ranitidine medications were unfit for their intended and ordinary purpose because the ranitidine medications manufactured, distributed, and sold by Defendant were defective in that they contained elevated levels of carcinogenic and liver-toxic NDMA, and as such are not generally recognized as safe for human consumption. As a result, Plaintiff and members of the Class and New York Subclass did not receive the goods as impliedly warranted by Defendant to be merchantable.

36. Plaintiff and members of the Class and New York Subclass purchased the ranitidine medications in reliance upon Defendant's skill and judgment and the implied warranties of fitness for the purpose.

37. The ranitidine medications were not altered by Plaintiff or members of the Class and New York Subclass.

38. The ranitidine medications were defective when it left the exclusive control of Defendant.

39. Defendant knew that the ranitidine medications would be purchased and used without additional testing by Plaintiff and members of the Class and New York Subclass.

40. The ranitidine medications were defectively manufactured and unfit for their intended purpose, and Plaintiff and members of the Class and New York Subclass did not receive the goods as warranted.

41. As a direct and proximate cause of Defendant's breach of the implied warranty, Plaintiff and members of the Class and New York Subclass have been injured and harmed because: (a) they would not have purchased the ranitidine medications on the same terms if they knew that the ranitidine medications contained harmful levels of NDMA, and are not generally recognized as safe for human consumption; and (b) the ranitidine medications do not have the characteristics, ingredients, uses, or benefits as promised by Defendant.

42. As a result of Defendant's breach of implied warranty, Plaintiff and each of the members of the Class and New York Subclass have been damaged in the amount of the purchase price of the ranitidine medications and any consequential damages resulting from the purchases.

COUNT II
Violation Of New York General Business Law § 349
(On Behalf Of The New York Subclass)

43. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

44. Plaintiff brings this claim individually and on behalf of the members of the proposed New York Subclass against Defendant.

45. New York's General Business Law § 349 prohibits deceptive acts or practices in

the conduct of any business, trade, or commerce.

46. In its sale of goods throughout the State of New York, Defendant conduct business and trade within the meaning and intendment of New York's General Business Law § 349.

47. Plaintiff and members of the New York Subclass are consumers who purchased products from Defendant for their personal use.

48. By the acts and conduct alleged herein, Defendant have engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, misrepresenting that its ranitidine medication (i) would not contain dangerously high levels of NDMA and (ii) is generally recognized as safe for human consumption.

49. The foregoing deceptive acts and practices were directed at consumers.

50. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and quality of its ranitidine medication to induce consumers to purchase the same.

51. By reason of this conduct, Defendant engaged in deceptive conduct in violation of New York's General Business Law.

52. Defendant's actions are the direct, foreseeable, and proximate cause of the damages that Plaintiff and members of the New York Subclass have sustained from having paid for and used Defendant's products.

53. As a result of Defendant's violations, Plaintiff and members of the New York Subclass have suffered damages because: (a) they would not have purchased Defendant's ranitidine medication on the same terms if they knew that Defendant's ranitidine medication contained high levels of NDMA; and (b) Defendant's ranitidine medication does not have the

characteristics, uses, benefits, or qualities as promised.

54. On behalf of herself and other members of the New York Subclass, Plaintiff seeks to recover her actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT III
Violation Of New York General Business Law § 350
(On Behalf Of The New York Subclass)

55. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

56. Plaintiff brings this claim individually and on behalf of the members of the proposed New York Subclass against Defendant.

57. New York's General Business Law § 350 prohibits false advertising in the conduct of any business, trade, or commerce.

58. Pursuant to said statute, false advertising is defined as "advertising, including labeling, of a commodity … if such advertising is misleading in a material respect."

59. Based on the foregoing, Defendant have engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of Section 350 of New York's General Business Law.

60. Defendant's false, misleading, and deceptive statements and representations of fact were and are directed towards consumers.

61. Defendant's false, misleading, and deceptive statements and representations of fact were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

62. Defendant's false, misleading, and deceptive statements and representations of

fact have resulted in consumer injury or harm to the public interest.

63. As a result of Defendant's false, misleading, and deceptive statements and representations of fact, Plaintiff and the New York Subclass have suffered and continue to suffer economic injury.

64. As a result of Defendant's violations, Plaintiff and members of the New York Subclass have suffered damages due to said violations because: (a) they would not have purchased Defendant's ranitidine medication on the same terms if they knew that Defendant's ranitidine medication contained elevated levels of NDMA and is not safe for human consumption; and (b) Defendant's ranitidine medication does not have the characteristics, uses, benefits, or qualities as promised.

65. On behalf of herself and other members of the New York Subclass, Plaintiff seeks to recover her actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT IV
Unjust Enrichment
(On Behalf Of The Class And New York Subclass)

66. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

67. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendant.

68. Plaintiff and the Class and New York Subclass conferred a benefit on Defendant in the form of monies paid to purchase Defendant's defective ranitidine medications.

69. Defendant voluntarily accepted and retained this benefit.

70. Because this benefit was obtained unlawfully, namely by selling and accepting

compensation for medications unfit for human use, it would be unjust and inequitable for the Defendant to retain it without paying the value thereof.

COUNT V
Fraudulent Concealment
(On Behalf Of The Class and New York Subclass)

71. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

72. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendant.

73. Defendant had a duty to disclose material facts to Plaintiff and the Class and New York Subclass given their relationship as contracting parties and intended users of the ranitidine-containing medications, including the ranitidine medications. Defendant also had a duty to disclose material facts to Plaintiff and the Class and New York Subclass, namely that they were in fact manufacturing, distributing, and selling harmful ranitidine-containing medications, including the ranitidine medications, containing NDMA that were unfit for human consumption. Such duty to disclose exists because Defendant had superior knowledge that the medications were defective and contained harmful levels of NDMA such that the transactions without the disclosure were rendered inherently unfair.

74. Defendant possessed knowledge of these material facts. In 2003, it was "proposed that elevated levels of NDMA in drinking water … may be associated with the drug ranitidine."[16] Likewise, in 2004, a study found the use of Zantac (the brand name for ranitidine) to be "related to the risk of bladder cancer."[17] Furthermore, a 2016 study by Stanford University

[16] VALISURE PETITION 4-5.

[17] Dominque S. Michaud et al., *Peptic Ulcer Disease and the Risk of Bladder Cancer in a Prospective Study of Male Health Professionals*, 13 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 250,

found that individuals who took ranitidine medications had "NDMA levels [in their urine] more than 400 times greater than what the FDA considers acceptable."[18] During that time, Plaintiff and members of the Class and New York Subclass were using the ranitidine medications without knowing it contained dangerous levels of NDMA.

75. Defendant failed to discharge their duty to disclose these materials facts.

76. In so failing to disclose these material facts to Plaintiff and the Class and New York Subclass, Defendant intended to hide from Plaintiff and the Class and New York Subclass that they were purchasing and consuming ranitidine medications with harmful defects that were unfit for human use, and thus acted with scienter and/or an intent to defraud.

77. Plaintiff and the Class and New York Subclass reasonably relied on Defendant's failure to disclose insofar as they would not have purchased the defective ranitidine medications manufactured, distributed, and sold by Defendant had they known the ranitidine medications contained unsafe levels of NDMA.

78. As a direct and proximate cause of Defendant's fraudulent concealment, Plaintiff and the Class and New York Subclass suffered damages in the amount of monies paid for the defective ranitidine medications.

79. As a result of Defendant's willful and malicious conduct, punitive damages are warranted.

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252 (2004) https://pdfs.semanticscholar.org/3eeb/c399404a2b100d90c6698bd4fc73a748864e.pdf(last accessed Apr. 21, 2020).

[18] Jonathan Lapook, *Potentially Dangerous Chemical Found in Popular Heartburn Pill Zantac*, CBS NEWS, Oct. 8, 2019, https://www.cbsnews.com/news/zantac-ndma-levels-potentially-dangerous-chemical-zantac-ranitidine-heartburn-pills-2019-10-08/ (last accessed Apr. 21, 2020).

COUNT VI
Fraud
(On Behalf Of The Class and New York Subclass)

80. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

81. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendant.

82. As discussed above, Defendant provided Plaintiff and members of the Class and New York Subclass with materially false or misleading information about their ranitidine-containing medications, including the ranitidine medications, manufactured by Defendant. Specifically, Defendant has marketed the ranitidine-containing medications as safe for human consumption. As indicated above, however, these representations are false and misleading as Defendant's ranitidine-containing medications contained elevated levels of NDMA.

83. The misrepresentations and omissions of material fact made by Defendant, upon which Plaintiff and members of the Class and New York Subclass reasonably and justifiably relied, were intended to induce and actually induced Plaintiff and members of the Class and New York Subclass to purchase the defective ranitidine medications.

84. Defendant knew that the ranitidine containing medications were contaminated with this harmful impurity, but continued to manufacture it nonetheless. In 2003, it was "proposed that elevated levels of NDMA in drinking water … may be associated with the drug ranitidine."[19] Likewise, in 2004, a study found the use of Zantac (the brand name for ranitidine) to be "related to the risk of bladder cancer."[20] Furthermore, a 2016 study by Stanford University

[19] VALISURE PETITION at 4-5.

[20] Dominque S. Michaud et al., *Peptic Ulcer Disease and the Risk of Bladder Cancer in a Prospective Study of Male Health Professionals*, 13 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 250,

found that individuals who took ranitidine medications had "NDMA levels [in their urine] more than 400 times greater than what the FDA considers acceptable."[21] During that time, Plaintiff and members of the Class and New York Subclass were using the medications without knowing that they contained dangerous levels of NDMA.

85. The fraudulent actions of Defendant caused damage to Plaintiff and members of the Class and New York Subclass, who are entitled to damages and other legal and equitable relief as a result.

86. As a result of Defendant's willful and malicious conduct, punitive damages are warranted.

COUNT VII
Conversion
(On Behalf Of The Class And New York Subclass)

87. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

88. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendant.

89. Plaintiff and the Class and New York Subclass have an ownership right to the monies paid for the defective ranitidine manufactured by Defendant.

90. Defendant has wrongly asserted dominion over the payments illegally diverted to them for the defective ranitidine medications. Defendant has done so every time that Plaintiff and the Class and New York Subclass bought the ranitidine-containing medications.

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252 (2004) https://pdfs.semanticscholar.org/3eeb/c399404a2b100d90c6698bd4fc73a748864e.pdf (last accessed Apr. 21, 2020).

[21] Jonathan Lapook, *Potentially Dangerous Chemical Found in Popular Heartburn Pill Zantac*, CBS NEWS, Oct. 8, 2019, https://www.cbsnews.com/news/zantac-ndma-levels-potentially-dangerous-chemical-zantac-ranitidine-heartburn-pills-2019-10-08/ (last accessed Apr. 21, 2020).

91. As a direct and proximate cause of Defendant's conversion, Plaintiff and the Class and New York Subclass suffered damages in the amount of the payments made for each time they were prescribed or paid money for the ranitidine medications.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, seeks judgment against Defendant, as follows:

(a) For an order certifying the Class and the New York Subclass under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiff as the representatives of the Class and New York Subclass and Plaintiff's attorneys as Class Counsel;

(b) For an order declaring the Defendant's conduct violates the statutes referenced herein;

(c) For an order finding in favor of Plaintiff, the Class, and the New York Subclass on all counts asserted herein;

(d) For compensatory, statutory, and punitive damages in amounts to be determined by the Court and/or jury;

(e) For prejudgment interest on all amounts awarded;

(f) For an order of restitution and all other forms of equitable monetary relief;

(g) For injunctive relief as pleaded or as the Court may deem proper; and

(h) For an order awarding Plaintiff and the Class and New York Subclass their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demand a trial by jury of any and all issues in this action so triable of right.

Dated: April 30, 2020

Respectfully submitted,

BURSOR & FISHER, P.A.

By: */s/ Andrew J. Obergfell*
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